



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

[Handwritten signature]

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/700,202	11/03/2003	Joseph J. McDonald	00988/4/US (6794-000053/C)	5566
7590	12/02/2005		EXAMINER	
TODD CRISSEY PFIZER INC., PFIZER PATENT DEPARTMENT-16/415S 2800 PLYMOUTH ROAD ANN ARBOR, MI 48105			BERNHARDT, EMILY B	
			ART UNIT	PAPER NUMBER
			1624	

DATE MAILED: 12/02/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/700,202	MCDONALD ET AL.	
	Examiner	Art Unit	
	Emily Bernhardt	1624	

— The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on ____.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) 1-14 and 21-27 is/are withdrawn from consideration.
- 5) Claim(s) ____ is/are allowed.
- 6) Claim(s) 15-20 and 28 is/are rejected.
- 7) Claim(s) ____ is/are objected to.
- 8) Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on ____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. ____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 2/2/05.
- 4) Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: ____.

Restriction to one of the following inventions is required under 35 U.S.C.

121:

- I. Claims 1-14 and 27, drawn to compounds, compositions , classified in class 546, subclasses such as 221,etc; class 514 subclass 327 and many others as determined by the exact nature of substituents thereon.
- II. Claims 15-19 and 28, drawn to compounds, compositions where Y=N, classified in class 544, subclasses such as 360,364,etc; class 514 subclass 253.01 and many others.
- III. Claims 15-20 and 28, drawn to compounds,compositions where Y=CH, classified in class 546, subclass 201,etc; class 514 subclass 323,etc.
- IV. Claims 21-23, drawn to multiple uses employing compounds of I, classified in class 514, subclass 327,etc.
- V. Claims 24-26, drawn to multiple uses employing compounds of II, classified in class 514, subclass 253.01,etc.
- VI. Claims 24-26, drawn to multiple uses employing compounds of III, classified in class 514, subclass 323,etc.

Consistent with parent, in addition to an election of one of the above groups, applicants must further elect one of the following subgroups:

- A. Where A1/A2 are acyclic or form together carbocyclic rings;
- B. Where A1/A2 form together heterocyclic rings.

In addition applicants must also elect a single species within the group/subgroup elected to which claims may be limited should generic claims be found not allowable.

If Groups IV-VI are elected applicants must a pick a single use.

The inventions are distinct, each from the other because of the following reasons:

Compounds within Groups I-III are drawn to a variety of piperazine, piperidine derivatives which are variously classified based on the nature of species which vary considerably from acyclic functional groups to many differing heterocyclic groups as evidenced at the very least by the species particularly embraced in the dependent claims. Such compounds are diversely classified and are not art-recognized equivalents. Art which may anticipate or render obvious one of these groups would not necessarily do the same for those remaining based on the structural dissimilarity of I vs II vs III vs IV, etc. as a whole.

Inventions I-III and IV-VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be

shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case more than one use exists for the many compounds being claimed as evidenced by entire classes being claimed.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended

during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

During a telephone conversation with Mr. Polster on 11/22/05 a provisional election was made with right of traverse to prosecute the invention of III and species of claim 20 in particular, claims 15-20 and 28. Affirmation of this election must be made by applicant in replying to this Office action. Claims 1-14 and 21-27 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Based on species elected Group IIIB has been held as constructively elected.

Claims 15-19 and 28 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject

matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. From a reading of the specification the scope of A1/A2 can entail any hetero ring regardless of size and degree of unsaturation as well as point of attachment to the sulfonyl group and be further substituted with an array of functional groups. The same applies to the scope of "heterocyclyl" as E3 with varying links at E1 and E2. While compounds have been made and tested these are consistently A1/A2 as pyrano substituted with E3 as mainly isoindolyl, isoquinolinyl with piperidino, piperazino, morpholino to a lesser extent. Only thiophene and furan are seen as examples of heteroaromatics. E2 choices are confined to C(O), C(O)-C(O), C(O)N, and N-C(O)C(O). For the compounds tested there is much evidence of structure-sensitivity by varying E1-E3 choices. There is thus no reasonable assurance as to what other rings will work.

Note In re Surrey 151 USPQ 724 regarding sufficiency of disclosure for a Markush group where as herein no examples of a diverse nature have been made much less tested showing the requisite activity needed to practice the invention. Also see

MPEP 2164.03 for enablement requirements in cases directed to structure-sensitive arts such as the pharmaceutical art. Also note the criteria for enablement as set out in In re Wands cited in MPEP 2164.01(a), August 2000 edition, which includes factors such as:

- 1) Breadth of the claims- the claims cover compounds easily in the billions;
- 2) Level of unpredictability in the art- the invention is pharmaceutical in nature involving inhibitory activity at one or more MMP receptors. It is well established that “the scope of enablement varies inversely with the degree of unpredictability of the factors involved” and physiological activity is generally considered to be unpredictable. Applicants’ own test data confirms this. See Table 9 . See In re Fisher 166 USPQ 18;
- 3) Direction or guidance- as stated above A1/A2 compounds actually made are much closer to each other than to remaining scope ;
- 4) State of the prior art- The compounds are sulfamato hydroxamic acid derivatives. While such compounds having this feature are also known in the art , they are similar in structure to the compounds made herein and thus do not evidence the many structural permutations permitted by the instant scope;

5) Working examples- While test data has been presented it is limited to the types of rings as discussed above and thus no clear evaluation of what other type of rings out of the many claimed might affect potency to a large or small degree.

In view of the above considerations, this rejection is being applied.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 15-19 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over DeCrescenzo (US'250 or WO'221, both cited by applicants). US'250 is applied as of its earlier provisional filing date of 2/8/99 and WO'221 was published more than a year earlier of applicants' earliest filing date. The reference describes many compounds with substituents thereon that are also exemplified herein for use as metalloprotease inhibitors. See Formula I which permits piperidine as NR^{3a}R^{3b} with E1 as alkylene, alkenylene and E2 as C(O) and E3 as piperdino and many other hetero rings. See cols 13-18 and col.670 in the US patent and pages 9-22 in the WO publication. Note that E1-E3 correspond to variables A-R-E-Y. While examples such as 49 in col.794 does not anticipate the

instant scope, it is structurally similar being substituted with a carbonyl between 2 piperdino rings vs instant E1 which requires an alkylene or alkenylene link attached to the central ring. However DeCrescenzo teaches alkylene, alkenylene as direct links to the central ring as can be seen in the definition of A and/or R with variable E including C(O) and many other moieties instantly embraced. See cols.17-18. Thus it would have been obvious to one skilled in the art at the time the instant invention was made to modify the carbonyl linking group in example 49 with a hydrocarbyl chain and in so doing obtain additional compounds with the expectation that they too will be metalloprotease inhibitors in view of the equivalency teachings outlined above.

Note that claim 20 is not rejected since the isoindolyl species is not particularly taught by DeCrescenzo.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 15-20 and 28 are rejected under 35 U.S.C. 102(e) as being

anticipated by Barta (WO'247). The commonly assigned publication which lists the same earlier provisional priorities as applicants claim, describes many compounds within the instant scope including the species of claim 20. The publication is 800+ pages long but from a computer-assisted search the relevant species were found. A copy of the abstract and structures are provided herewith. The WO publication is being applied as of its filing date of 4/25/03. Note that said publication has a different inventive entity than herein. It is recognized applicants are claiming benefit under 35 USC 120 as well as under 119(e). However to obtain such benefit there must be compliance with 35 USC 112, first paragraph-description and enablement. However, benefit cannot be granted since all claims rejected herein except claim 20, fail to comply with 35 USC 112 par.one for the reasons set forth in the above 112 rejection. Additionally, the subject matter claimed herein is not seen to be entirely described in earlier parent and not at all in provisional cases. Compare scope at E1-E3 with that described in parent. Note MPEP 201.11, 201.15 and 35 USC 119 (e), on page L-23, Rev. 2 May 2004.

Applicants' IDS of 2/02/05 is acknowledged and considered. The list of copending applications, which have been seen by the examiner, need to be inserted into "**Other Documents**" section in compliance with MPEP 609. Once resubmitted they will be indicated as considered.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Emily Bernhardt whose telephone number is 571-272-0664.

If attempts to reach the examiner by telephone are unsuccessful, the acting supervisor for AU 1624, James O. Wilson can be reached at 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.



Emily Bernhardt
Primary Examiner
Art Unit 1624